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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/772,607	01/30/2001	Ib Jonassen	4409-214-US	2082

23650 7590 05/08/2008  
NOVO NORDISK, INC.  
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PRINCETON, NJ 08540

EXAMINER
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KAM, CHIH MIN

ART UNIT	PAPER NUMBER
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1656

NOTIFICATION DATE	DELIVERY MODE
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05/08/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

nnipatent@novonordisk.com  
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<b>Office Action Summary</b>	<b>Application No.</b> 09/772,607	<b>Applicant(s)</b> JONASSEN ET AL.	
	<b>Examiner</b> CHIH-MIN KAM	<b>Art Unit</b> 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 February 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 48-59 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 48 and 49 is/are rejected.
- 7) ☒ Claim(s) 50-59 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                      |                                                                   |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____                                                          | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Status of the Claims*

1. Claims 48-59 are pending.

Applicants' amendment and response filed February 7, 2008 is acknowledged, and applicants' response has been fully considered. Thus, claims 48-59 are examined.

### *Maintained Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –  
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 48 and 49 remain rejected under 35 U.S.C. 102(b) as anticipated by Habener (U.S. Patent 5,120,712, publication date: June 9, 1992).

Habener teaches a GLP-1 derivative having a formula  $H_2N-X-CO-R^1$ , where X is the peptide comprising the sequence His-Ala-Glu-Gly-Thr-Phe-Thr-Ser-Asp-Val-Ser-Ser-Tyr-Leu-Glu-Gly-Gln-Ala-Ala-Lys-Glu-Phe-Ile-Ala-Trp-Leu-Val-Lys-Gly-Arg-Gly;  $R^1$  is OH, OM or  $-NR^2R^3$ ; M is a pharmaceutically acceptable cation or a lower ( $C_1-C_6$ ) branched or unbranched alkyl group; and  $R^2$  and  $R^3$  are each hydrogen or a lower ( $C_1-C_6$ ) branched or unbranched alkyl group (column 4, lines 1-25). The  $NH-R^2R^3$  group, which can contain 12 carbon ( $C_6$  for both  $R^2$  and  $R^3$ ) and an amino group, is attached to the C-terminus amino acid without a spacer, thus the GLP-1 derivative taught by Habener *et al.* meets the criteria of claims 48 and 49 (i.e., a lipophilic substituent having 8 to 40 carbon atoms and optionally having an amino group is attached to the C-terminal amino acid of GLP-1 or the analog thereof).

Response to Arguments

Applicants indicate that claims 48 and 49 recite that "a lipophilic substituent having 8 to 40 (or 12 to 35 in claim 49) carbon atoms .... is .... attached to the C-terminal amino acid of GLP-1 or the analog thereof...". Thus, a single lipophilic substituent of 8-40 or 12-35 carbon atoms is attached to the C-terminal amino acid in pending claims 48 and 49 respectively. However, the disclosure in the cited Habener patent at col. 4, lines 1-25 that the C- terminus of the GLP-1 can be  $NR^2R^3$  where  $R^2$  and  $R^3$  can each be  $C_1$ - $C_6$  alkyl does not describe a single lipophilic substituent of 12 carbons attached to the C-terminus. Rather Habener describes the attachment of two lipophilic substituents, each of up to 6 carbon atoms in length, to the C-terminal amino acid of GLP-1. Thus, Habener does not anticipate claims 48 and 49 and withdrawal of this rejection is respectfully requested (page 4 of the response).

Applicants' response has been considered, however, the arguments are not found persuasive because of the following reasons. While the lipophilic substituent of claim 48, which is attached to the C-terminal amino acid of GLP-1, contains 8 to 40 carbons (12 to 35 carbons for claim 49) and optionally an amino group, the claim does not specifically indicate how these carbon atoms are arranged in the lipophilic substituent. Thus, the  $NR^2R^3$  group, which contains total of 12 carbons (i.e.,  $C_6$  for both  $R^2$  and  $R^3$ ) and is attached to the C-terminal amino acid of GLP-1, reads as the lipophilic substituent and meets the limitation of claims 48 and 49. Therefore, the rejection is maintained.

***Claim Objection***

3. Claims 50-59 are objected to as being dependent upon a rejected base claim.

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***Conclusions***

4. Claims 48-49 are rejected, and claims 50-59 are objected to.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Bragdon can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Chih-Min Kam/

Primary Examiner, Art Unit 1656

CMK

May 5, 2008